REMARKS

In this Amendment, claims 30, 31, 36, 47 and 53 are currently amended. Claims 32-34, 37-45, 48-52, and 54-64 remain as previously presented and claims 1-29, 35 and 46 remain canceled without prejudice or disclaimer. The amendments to the claims are fully supported by the specification of the application as filed. No new matter has been introduced into the application by virtue of the amended claims. More specifically, support for the amendment in claims 30, 31 and 47 is found in the instant specification on page 19, line 13. Support for the amendment in claim 36 is found in the instant specification on page 19, line 14. Claim 53 has been amended to correct dependency. Accordingly, the currently pending claims are now claims 30-34, 36-45 and 47-64.

Double Patenting

Claims 30-32, 34, 47 and 52-61 were provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 29-34, 36-41, 46 and 47 of co-pending application U.S. Serial No. 10/461,393 (hereinafter "the '393 application"). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

In the Advisory Action dated June 6, 2005, the Examiner states that "[a]pplicants argue that the difference between the two sets of claims is that in the co-pending '393 application the molecular weight of the amylopectin is specifically reduced by acid hydrolysis whereas in the starch of the instant claims the molecular weight of the amylopectin is reduced by shearing. A comparison of the starches of the instant and the copending claims shows that the characteristics like molecular weight ranges, purity levels and dissolution characteristics in water are identical." The Examiner concludes that "[t]he mode of molecular weight reduction is not seen to render the starch claimed in either application patentably distinct" and that the submitted declaration of Dr. Jones "is an opinion that is not seen to overcome the statutory 101 double patenting rejection".

It is respectfully submitted that claims 30-32, 34, 47 and 52-61 of the instant application are drawn to a pharmaceutically acceptable starch that is **not** the same as that described in claims

29-34, 36-41, 46 and 47 of the '393 application. In the instant case, the claims are directed to a pharmaceutically acceptable starch and microparticles based on this starch, in which the starch has undergone molecular weight reduction by shearing. Claims 29-34, 36-41, 46 and 47 of the co-pending '393 application are directed to a starch in which the molecular weight of amylopectin is specifically reduced by acid hydrolysis.

As currently amended, the instant claims reflect that the molecular weight of amylopectin has been reduced by shearing to obtain a molecular weight distribution in which at least 80 percent by weight of the starch lies within the range of 100-4000 kDa. The starch product claimed in the instant application and the starch product claimed in the '393 application are considered to be distinct and non-overlapping products, as a more narrow molecular weight distribution of the resulting starch fragments is obtained by shearing versus acid hydrolysis to reduce the molecular weight of amylopectin comprising the starch.

In addition, the second declaration of Dr. Richard Jones, of record, provides and describes experimental evidence demonstrating the differences between sheared starch and acid hydrolyzed starch. Thus, the presently claimed invention in which shearing is used for molecular weight reduction yields a starch product that is discernibly different from that produced by acid hydrolysis. It is respectfully submitted that the use of acid hydrolysis versus shearing to reduce the molecular weight of the resulting starch product is to be given consideration in the claims.

In view of the currently-presented claims and the first and second declarations of Dr. Richard E. Jones under 37 C.F.R. §1.132, of record in this application, it is respectfully submitted that the claims of the instant application and those of the '393 application are not identical. Applicants therefore submit that the currently amended claims and claims 29-34, 36-41, 46 and 47 of the '393 application are not directed to the same invention. Accordingly, withdrawal of the 35 U.S.C. §101 rejection is respectfully requested.

Further, to progress this application in the Patent Office and as previously discussed with the Examiner, Applicants submit herewith a terminal disclaimer and accompanying

documentation and fee, to obviate a potential rejection of the currently pending claims under the judicially created doctrine of obviousness double patenting in view of claims 29-34, 36-41, 46 and 47 of co-pending patent application U.S. Serial No. 10/461,393.

CONCLUSION

Applicants respectfully submit that the present application is now in condition for allowance. An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this Amendment, or during the pendancy of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. **50-0311**; Reference No. **28069-585-DIV**; Customer No. **35437**. Should an extension of time be required in this application, the Commissioner is hereby requested to grant a petition for an extension of time such as may be required, and to charge any fee(s) related thereto, to the aforementioned Deposit Account No., Reference No. and Customer No.

If the Examiner believes that further discussion of the application would be helpful, he is respectfully requested to telephone the Applicants' undersigned representative at (212) 692-6742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

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